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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,907	03/08/2004	Svetlana Gramatikova	564462004220	2676

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EXAMINER	
DEJONG, ERIC S	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,907	GRAMATIKOVA ET AL.	
	Examiner	Art Unit	
	Eric S. DeJong	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,5,6,8,24,27,31,33,34,38-43,46,49,51,53,55,57,60,61,65,66,83,84,93,94,98,100-102,104-108,110-114,118,123,128,130,133,143-146,148,152,153,158,160,164,165,168-171,174,175,178,181-183,197,200,205,212 and 227-231.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,5,6,8,24,27,31,33,34,38-43,46,49,51,53,55,57,60,61,65,66,83,84,93,94,98,100-102,104-108,110-114,118,123,128,130,133,143-146,148,152,153,158,160,164,165,168-171,174,175,178,181-183,197,200,205,212 and 227-231.

DETAILED OFFICE ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 6, 8, 24, 27, 31, 33, 34, 41-43, 46, 55, 164, 168 drawn to an isolated or recombinant nucleic acid sequence, a nucleic acid probe for identifying a nucleic acid encoding a polypeptide with a phospholipase activity, an amplification primer sequence pair, a phospholipase-encoding nucleic acid, an expression cassette comprising a nucleic acid, a vector comprising a nucleic acid, a cloning vehicle comprising a nucleic acid, a transformed cell comprising a nucleic acid, an antisense oligonucleotide, an isolated or recombinant signal sequence, and an isolated or recombinant nucleic acid sequence encoding a chimeric polypeptide, classified in class 536, subclass 23.1.

II. Claims 38, 61, 65, 66, 83, 84, 93, 94, 98, 102, 104, 165 drawn to an isolated or recombinant phospholipase, an isolated or recombinant polypeptide, a protein preparation comprising a polypeptide, a heterodimer or homodimer comprising a polypeptide, an immobilized polypeptide, an isolated or recombinant antibody that specifically binds to a polypeptide, a hybridoma comprising an antibody that specifically binds to a polypeptide, and a chimeric polypeptide classified in class 530, subclass 350.

III. Claim 39, drawn to a method of amplifying a nucleic acid encoding a polypeptide having a phospholipase activity, classified in class 435, subclass 91.2.

IV. Claims 40, drawn to a method for making a phospholipase, classified in class 435, subclass 69.1.

V. Claim 49, drawn to a transgenic non-human animal, classified in class 800, subclass 13.

VI. Claims 51 and 53, drawn to a transgenic plant and a transgenic seed, classified in class 800, subclass 13.

VII. Claims 57, 58, 60, a method of inhibiting the translation of a phospholipase message in a cell, a double stranded inhibitory RNAi molecule, classified in class 514, subclass 44.

VIII. Claim 100, drawn to an array comprising an immobilized polypeptide, classified in class 422, subclass 50.

IX. Claim 101, drawn to an array comprising an immobilized nucleic acid, classified in class 422, subclass 50.

X. Claim 105 and 110-113, drawn to a method for identifying a polypeptide having phospholipase activity, a method of identifying a phospholipase substrate, a method of determining whether a test compound specifically binds to a polypeptide, classified in class 702, subclass 19.

XI. Claims 106-108, drawn to a method of isolating or identifying a polypeptide with a phospholipase activity, a method of making an anti-

phospholipase antibody and a method of producing a recombinant polypeptide, classified in class 435, subclass 69.1.

XII. Claim 114, drawn to a method for identifying a modulator of phospholipase activity, classified in class 702, subclass 19.

XIII. Claim 118, drawn to a computer system or a computer readable medium comprising a processor and a data storage device having a polypeptide or a nucleic acid sequence disposed thereon, classified in class 707, subclass 102.

XIV. Claim 123, drawn to a method for identifying a feature in a sequence, classified in class 702, subclass 19.

XV. Claims 128 and 130, drawn to a method for isolating or recovering a nucleic acid encoding a polypeptide with a phospholipase activity from an environmental sample, classified in class 435, subclass 183.

XVI. Claims 133 and 143-146, drawn to a method of generating a variant of a nucleic acid encoding a polypeptide with a phospholipase activity and a method for modifying codons in a nucleic acid encoding a polypeptide with a phospholipase activity, classified in class 435, subclass 6.

XVII. Claim 148, drawn to a method for producing a library of nucleic acids encoding a plurality of modified phospholipase active sites or substrate binding sites, classified in class 435, subclass 4.

XVIII. Claim 152, drawn to a method for making a small molecule and a method for modifying a small molecule, classified in class 702, subclass 22.

XIX. Claim 158, drawn to a method for determining a functional fragment of a phospholipase enzyme, classified in class 702, subclass 19.

XX. Claim 160, drawn to a method for whole cell engineering of a new or modified phenotypes by using real-time metabolic flux analysis, classified in class 435, subclass 243.

XXI. Claim 169, drawn to a method of increasing thermotolerance or thermostability of a phospholipase, classified in class 702, subclass 19.

XXII. Claim 170, drawn to a method of overexpressing a recombinant phospholipase in a cell, classified in class 435, subclass 69.1.

XXIII. Claims 171 and 174, drawn to a method of making a transgenic plant and a method of expressing a heterologous nucleic acid sequence in a plant cell, classified in class 800, subclass 13.

XXIV. Claims 175, 178, 182, 183, 197, 200, 227 drawn to a method for hydrolyzing, breaking up, or disrupting a phospholipids-comprising composition, a method of washing an object, a method of degumming an oil, a method for converting a non-hydratable phospholipids to a hydratable form, a method for caustic refining of a phospholipids-containing composition, and a method for degumming an oil or a fat classified in class 435, subclass 264.

XXV. Claims 181 and 228, drawn to a detergent composition comprising a polypeptide and a composition having the equivalent of a phospholipase C activity, classified in class 435, subclass 262.

XXVI. Claim 205, drawn to a method for purification of a phytosterol or a triterpene, classified in class 702, subclass 22.

XXVII. Claim 212, drawn to a method for refining a crude oil, classified in class 435, subclass 281.

XXVIII. Claims 229-231, drawn to a method of ameliorating or preventing lipopolysaccharide-mediated toxicity, a method for detoxifying an endotoxin, and a method for deacylating a 2' or 3' fatty acid.chain comprising contact with a polypeptide classified in class 514, subclass 2.

Groups I-XXVIII are further subject to the nucleic acid and polypeptide sequence election requirement set forth below.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group II are directed to related nucleic acid compositions and polypeptide sequences encoded thereby. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the molecular structure of the nucleic acid sequences of Group I is materially different from the molecular structure of the polypeptide sequences of Group II. Further the operation, function, and effect of nucleic acid sequences of Group I are materially distinct from that

of the polypeptide sequences for Group II. Further the search required for any of the nucleic acid sequences of Group I would not be coextensive with the search require for any of the polypeptide sequences of Group II, and therefore present an undue burden of search if Groups I and II are searched together.

Inventions of Group I and Groups III, XV, XVI, XVII, and XXIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the nucleic acid sequences of Group I can be made by the distinct methods as set forth in Groups III, XV, XVI, XVII, and XXIII.

Inventions of Group II and Groups IV, X, XI, XIX, and XXII are related as process of making and product made. In the instant case the polypeptide sequences of Group II can be made by the distinct methods as set forth in Groups IV, X, XI, XIX, and XXII.

Inventions of Group I and II and Groups V, VI, VII, VIII, IX, XII, XIII, XIV, XIII, XX, XXI, XXIV, XXV, XXVI, XXVII, and XXVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acid sequences of Group I and the polypeptide products of Group II can be used in the distinct methods of Groups V, VI, VII, VIII, IX, XII, XIII, XIV, XIII, XX, XXI, XXIV,

XXV, XXVI, XXVII, and XXVIII that require either a nucleic acid sequence as set forth in Group I or a polypeptide sequence as set forth in Group II.

Inventions Groups III, IV, X, XI, XV, XVI, XVII, XIX, XXII, and XXIII are directed to related methods of making and identifying nucleic acid sequences or polypeptide sequences. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed in Groups III, XV, XVI, XVII, and XXIII are directed to are directed to processes of making or identifying a nucleic acid product. In contrast, the inventions as claimed in Groups IV, XI, X, XIX, and XXII are directed to making or identifying a polypeptide sequence product. Further, the inventions as claimed in Groups III, XV, XVI, XVII, and XXIII are distinct, each from the other, because they of materially different designs and modes of operation. Further, the inventions as claimed in Groups IV, XI, X, XIX, and XXII are distinct, each from the other, because they are of materially different designs and modes of operation. Furthermore, the inventions as claimed do not encompass overlapping subject matter.

Inventions Groups V, VI, VII, VIII, IX, XII, XIII, XIV, XIII, XX, XXI, XXIV, XXV, XXVI, XXVII, and XXVIII are directed methods related by the use of the nucleic acid sequences or polypeptide sequences products of Groups I and II. In the instant case, the inventions as claimed in Groups V, VI, VII, VIII, IX, XII, XIII, XIV, XIII, XX, XXI, XXIV, XXV, XXVI, XXVII, and XXVIII are distinct, each from the other, because they of

materially different designs, modes of operation, functions, and effects. Furthermore, the inventions as claimed do not encompass overlapping subject matter.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Nucleic Acid and Polypeptide Election Requirement

The claimed inventions of Groups I-XXVIII read on patentably distinct nucleic acid sequences and polypeptide sequences. MPEP § 803.04 states:

> Polynucleotide molecules defined by their nucleic acid sequence (hereinafter "nucleotide sequences") that encode different proteins are structurally distinct chemical compounds. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 USC § 121 and 37 CFR § 1.141 et seq.

Therefore the nucleic acid sequences and polypeptide sequences as claimed are considered to constitute independent and distinct inventions with the meaning of 35 USC 121. For nucleic acid sequences and polypeptide sequences, the Applicants must elect either a single disclosed nucleic acid sequence or a single disclosed polypeptide sequence (See MPEP 803.04). Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a species election requirement.

Applicants is advised that the reply to this restriction requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER